Page 2 Dkt: 875.085ŪS1

COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED Title:

DISORDERS

IN THE SPECIFICATION

Please amend the paragraph beginning on page 43, line 15 as follows:

These formulations can contain pharmaceutically acceptable vehicles and adjuvants which are well known in the prior art. It is possible, for example, to prepare solutions using one or more organic solvent(s) that is/are acceptable from the physiological standpoint, chosen, in addition to water, from solvents such as acetone, ethanol, isopropyl alcohol, glycol ethers such as the products sold under the name "Dowanol", polyglycols and polyethylene glycols, C₁-C₄ alkyl esters of short-chain acids, preferably ethyl or isopropyl lactate, fatty acid triglycerides such as the products marketed under the name MIGLYOL® "Miglyol". isopropyl myristate, animal, mineral and vegetable oils and polysiloxanes.

Please amend the table beginning on page 75 as follows:

Table 2. In Vivo Enhancement of FVIII rAAV Transduction

Day 14 Results		
Sample	Animal # and Final Result ([[DF*]]ng/mL) Coatest (mU/mL)	
Group 1 Vehicle		
	801 < 0.63	0
	804 < 0.63	0
	805 < 0.63	0
	847 < 0.63	0
Group 2 AAV2/5-HFN3/EBP-FVIII		
	816 < 0.63	0
	817 < 0.63	0
	818 0.92	0
	819 < 0.63	0
	820 < .63	0
	834 0.9	0
Group 2 AAV2/5-HFN3/EBP-FVIII + Dox	cil .	
	870 60.45	171
	871 26.29	0

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116 – EXPEDITED PROCEDURE

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Title: COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED DISORDERS

872 12.395	14
873 44.3	30
874 12.135	122
875 31.04	94

2.X.10, Day 25 FVIII ELISA

Sample	Animal # and Final Result			
Group 1 Vohiolo				
Group 1 Vehicle		_		
	806 < 0.63	0		
	807 < 0.63	0		
	808 < 0.63	0		
	849 < 0.63	0		
Group 2 AAV2/5-HFN3/EBP-FVIII				
	821 < 0.63	0		
	822 < 0.63	0		
	823 < 0.63	0		
	824 1.27	0		
	825 0.72	0		
	833 0.74	0		
Group 3 AAV2/5-HFN3/EBP-FVIII + Doxil (no spikes)				
Gloup 3 AA V 2/3-111 143/EB1 -1 VIII BOXI		40.022		
	841 16.785	49.833		
	842 12.425	37.282		
	843 13.685	41.466		
	844 35.225	91.842		
	845 7.815	12.974		
	846 24.02	54.853		